

### **REMARKS**

The invention relates to a substance delivery device particularly useful for the delivery of drugs for use in animal body cavities, such as a vagina. The substance delivery device includes a support frame having at least two resilient arms which retain the substance delivery device inside the body cavity and against mucosal membranes of the body cavity, wherein each arm is capable of releasing a separate pod capable of releasing a drug contained within a matrix of the pod, wherein each distal end of the two resilient arms and pods attached to the arms are biased outward from a central section of the support frame and wherein at least one of the pods is flexibly attached to a corresponding arm by a ball and socket mechanism allowing full movement of the pod with respect to the support frame and enabling the substance delivery device to contact the mucosal membranes within the body cavity.

Upon entry of the present amendment, Claims 1, 3-5, 8-9, 11, 14 and 21 will be pending in this application. Claims 1, 4 and 21 are currently amended. Claims 2, 6-7, 10, 12-13 and 15-20 are cancelled without prejudice. No new matter is added and support for the amendments can be found throughout the instant application.

### ***Allowable Subject Matter***

In the Non-Final Office Action mailed November 11, 2006, the Examiner objected to Claim 7 for being dependent upon a rejected base claim, but stated the claim would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claim. Applicants respectfully submit that Claim 7 was cancelled in the Amendment and Response to Office Action filed October 16, 2007, and that the subject matter of Claim 7 was incorporated into Claim 1. Accordingly, applicants respectfully submit Claim 1 is in the form for allowance and kindly request issuance of a Notice of Allowance.

***Rejections based on 35 U.S.C. §102(b)***

In the Final Office Action mailed July 14, 2008, Claims 1, 4-5, 8, 12-13 and 17 were rejected under 35 U.S.C. §102(b) as being anticipated by Hiller *et al.*, (US 4,369,783). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite that the internal substance delivery device is inserted and retained within the body cavity, and that each **distal end of the two resilient arms and pods attached to the arms are biased outward** from a central section of the support frame. Applicants respectfully submit that support for the above amendments can be found throughout the instant application.

In particular, applicants kindly direct the Examiner to page 5, lines 17-21, of the instant application as International Publication Number: WO 99/18884, that states that “[t]he tension along the length of the arms can cause the **arms to bias outwards** from the body of the support frame causing the arms or the substance **delivery pods attached to arms to extend outwards** toward the mucosal membrane” (emphasis added).

Further support for the above amendment can be found on, at least, page 12, lines 7-8 of WO 99/18884, that states “[t]he arms 4 and 5 are curved in such a manner that when *in situ* (refer Figure 1) the **distal ends of the arms 7 are biased outward**” (emphasis added).

Applicants respectfully submit that Hiller *et al.*, fails to teach or suggest all of the claim limitations and is not therefore a proper prior art reference under 35 U.S.C. §102(b). Applicants respectfully assert that Hiller *et al.*, fails to teach or suggest a support frame having at least two resilient arms wherein **each distal end of the at least two resilient arms and pods attached to the arms are biased outward**.

Hiller *et al.*, teaches “a nose-clip consisting of a resilient, U-Shaped element hereinafter named “bow”, **whose terminal parts are inclined towards each other**” (emphasis added) See column 1, lines 25-34.

Column 1, lines 39-45 of Hiller *et al.*, also disclose a nose-clip “***whose ends are inclined towards each other and turned to face each other***” (emphasis added).

Claim 1 and Figures 1, 16 and 17, of 4,369,783 disclose that “***each end of the bow portion and said receiving means being inclined towards each other*** to form an inclination angle  $\alpha$  with respect to the symmetrical axis of said bow portion and turned in same direction from said first plane to form a torsion angle  $\beta$  with respect to a plane normal to said first plane thereby insuring ***that the surfaces of any depot bodies mounted thereon are inclined towards each other and turned to face each other*** for positioning in the nasal vestibules of cattle”.

For at least the above reasons, applicants respectfully submit that Hiller *et al.*, fails to teach or suggest that each distal end of the two resilient arms and pods attached to the arms are biased outward. Accordingly, applicants submit that they have overcome the rejection under 35 U.S.C. §102(b) and kindly request withdrawal of the rejection. Applicants respectfully submit that Claims 4-5 and 8 are also novel and non-obvious given their direct dependence on amended Claim 1. Claims 12-13 and 17 are cancelled herein, rendering the rejection moot.

#### ***Rejections based on 35 U.S.C. §103(a)***

In the Final Office Action mailed July 14, 2008, Claim 11 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite **structural features** of the internal substance delivery device that are not taught or suggested by Hiller *et al.* Claim 11 depends indirectly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite that **each distal end of the two resilient arms and pods attached to the arms are biased outward** from a central section of the support frame.

Applicants submit that Hiller *et al.*, discloses a nose-clip device wherein the distal ends of the device (bow) are **inclined towards each other**. Furthermore, Hiller *et al.*, discloses that the **receiving depots** (that are similar to the pods of the instant invention) **are turned to face each other** (see Claim 1 of 4,369,783). It is clear then, that if the distal ends are inclined towards each other and that the receiving depots are faced toward each other **they cannot also be biased outward**. Accordingly, Hiller *et al.*, fails to teach, suggest or provide motivation to one of ordinary skill in the art to derive the claimed invention.

If one of ordinary skill in the art were to use the device of Hiller instead of the device as recited in amended Claim 1, one could conclude that the device **would not be retained within the body cavity** because there would be no **outward tension** provided by the distal end of the arms of Hiller's device **to keep the device in place**, i.e., against the walls of the body cavity. Accordingly, Hiller's device could exit through an animals entrance orifice under natural conditions. In contrast, the claimed invention is designed to be retained within the body cavity through the use of each distal end of the two resilient arms and pods attached to the arms to contact the walls of the body cavity (see page 1, lines 13-18 of WO 99/18884).

Finally, with respect to motivation of one of ordinary skill in the art to derive the claimed invention, if one were to modify the device of Hiller to include outwardly biased arms or pods attached to the arms (as taught herein), there would be no tension in the outwardly biased arms to attach the nose-clip to the nasal septum. Therefore, destroying the functionality of Hiller's device. Accordingly, one of ordinary skill in the art would not be motivated to derive the claimed invention for at least the above reasons. Applicants respectfully submit that Claim 11 is novel and non-obvious. Accordingly, applicants kindly request withdrawal of the rejection of Claim 11 under 35 U.S.C. §103(a).

In the Final Office Action mailed July 14, 2008, Claim 20 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 20 is cancelled herein, rendering the rejection moot. Accordingly, applicants kindly request withdrawal of the rejection of Claim 20 under 35 U.S.C. §103(a).

In the Final Office Action mailed July 14, 2008, Claim 3 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record) in view of Anderson *et al.*, (US 5,816,248). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite **structural features** of an internal substance delivery device that are not taught or suggested by Hiller *et al.*, or Anderson *et al.* Applicants respectfully submit Claim 3 depends directly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite that **each distal end of the at least two resilient arms and pods attached to the arms are biased outward** from a central section of the support frame. Applicants respectfully submit that Hiller *et al.*, alone, or combination with Anderson *et al.*, fails to teach or suggest the claimed invention for at least the following reasons.

As discussed under 35 U.S.C. rejection under §102(b), Hiller *et al.*, fails to teach or suggest that the **distal ends of the “bow” nose-clip are biased outward**. Additionally, Hiller *et al.*, fails to teach that the pods attached to the distal ends of the arms are biased outward. In fact, Hiller *et al.*, discloses that **both the distal ends and the receiving depots** (that are similar to the pods of the instant invention) **are inclined inward**. Applicants respectfully assert Hiller *et al.*, discloses biased inward arms that “are **inclined towards each other**” (see column 1, lines 39-45). Furthermore, the deficiencies of Hiller *et al.*, are not satisfied by Anderson *et al.*, for at least the following reasons.

Anderson *et al.*, fails to teach or suggest an internal substance delivery device wherein the at least one pod is **flexibly attached** to a corresponding arm by a **ball and socket mechanism**.

Additionally, Anderson *et al.*, fails to teach or suggest that the at least one pod attached to the corresponding arm by a ball and socket mechanism **allows full movement of the pod with respect to the support frame**, such that the pod is in contact with the mucosal membrane of the body cavity.

Furthermore, Anderson *et al.*, fails to teach a device comprising **at least two resilient arms**; and wherein each distal end of the two resilient **arms are biased outward**. Additionally, Anderson *et al.*, fails to teach a device that comprises pods that are attached to the distal ends of the two resilient arms and that both the **distal ends of the resilient arms and the pods are biased outward**.

Applicants respectfully submit there is no suggestion or motivation to one of ordinary skill in the art to modify the device of Hiller *et al.*, to incorporate the device of Anderson *et al.*, because doing so **would not fulfill the shortcomings of both references** to derive the claimed invention. As discussed above, under the rejection of Claim 11 under 35 U.S.C. §103(a), modifying the Hiller device to incorporate outwardly biased arms or outwardly biased pods attached to the arms would **destroy the functionality of the Hiller device**. The Hiller device is a nose-clip for cattle that requires inward inclined distal ends and receiving depots so that the device can attach to the nasal septum (see Figure 1 of Hiller). With outward inclined arms (as claimed herein) the Hiller device would no longer be able to attach to the nasal septum and would be rendered **non-functional**. For at least the above reasons, and the dependency of Claim 3 on amended Claim 1, applicants respectfully submit that Claim 3 is novel and non-obvious. Accordingly, applicants kindly request withdrawal of the rejection of Claim 3 under 35 U.S.C. §103(a).

In the Final Office Action mailed July 14, 2008, Claim 9 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record) in view of Anderson *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite **structural features** of an internal substance delivery device that are not taught or suggested by Hiller *et al.*, or Anderson *et al.* Applicants respectfully submit Claim 9 depends directly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite that **each distal end of the at least two resilient arms and pods attached to the arms are biased outward**. Applicants respectfully submit that Hiller *et al.*, alone, or combination with Anderson *et al.*, fail to teach or suggest the claimed invention. Specifically, applicants respectfully submit Hiller *et al.*, discloses **biased inward** arms that “are **inclined towards each other**” (see column 1, lines 39-45). Anderson *et al.*, also fails to teach or suggest an internal substance delivery device comprising at least two resilient arms or pods attached to the arms; wherein the arms or pods are **biased outward**.

Based on the dependency of Claim 9 on amended Claim 1, applicants respectfully submit that Claim 9 is now in a form for allowance. Accordingly, applicants kindly request withdrawal of the rejection of Claim 9 under 35 U.S.C. §103(a).

In the Final Office Action mailed July 14, 2008, Claims 14, 18 and 19 were rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record) in view of Anderson *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claims 18 and 19 are cancelled herein, rendering the rejection moot. With respect to Claim 14, Claim 14 is dependent upon amended Claim 1. As discussed above under 35 U.S.C. §102(b) and §103(a), Claim 1 is novel and non-obvious in view of Hiller *et al.*, and Anderson *et al.* Claim 1 is amended herein to recite **structural features** of an internal substance delivery device that are not taught or suggested by Hiller *et al.*, or Anderson *et al.* Applicants have amended Claim 1 to recite that **each distal end of the at least two resilient arms and pods attached to the arms are biased outward** from the support frame. Applicants respectfully submit that

Hiller *et al.*, alone, or combination with Anderson *et al.*, fail to teach or suggest the claimed invention.

As discussed above, Hiller *et al.*, fails to teach **biased outward** resilient arms. Furthermore, Anderson *et al.*, fails to teach or suggest an internal substance delivery device wherein the at least one pod is **flexibly attached** to a corresponding arm by a **ball and socket mechanism**. Additionally, Anderson *et al.*, fails to teach or suggest that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the pod is in contact with the mucosal membrane of the body cavity.

Applicants respectfully submit there is no suggestion or motivation for one of ordinary skill in the art to modify the device's of Anderson *et al.*, and Hiller *et al.*, to derive the claimed invention. Based on the dependency of Claim 14 on amended Claim 1, applicants respectfully submit that Claim 14 is in the form for allowance. Accordingly, applicants kindly request withdrawal of the rejection under 35 U.S.C. §103(a).

#### ***Request for status of Claim 21***

Applicants respectfully submit that Claim 21 was rejected by the Examiner based on the Office Action Summary provided with the Final Office Action mailed July 14, 2008. However, applicants are unable to locate any discussion of Claim 21 or any rejection of Claim 21. Applicants submit that they have responded fully to the rejections raised in the Final Office Action mailed July 14, 2008, but cannot respond to the rejection of Claim 21 until the Examiner presents the rejection. Applicants kindly request **withdrawal of the finality of the Office Action mailed July 14, 2008**, in order to respond to the rejection of Claim 21. Alternatively, applicants request a Notice of Allowance based on the amendments to the claims and remarks provided herein in view of Hiller *et al.*, and Anderson *et al.*

With respect to the amendments of Claim 21 provided herein, support for the amendments can be found in currently pending Claim 3; page 3, lines 15-16 and page 8, lines 15-19 of the instant application.



**CONCLUSION**

In light of the amendments and the above remarks, Applicants are of the opinion that the Final Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to Dr. Zara Doddridge at (404)-815-6473 is respectfully solicited.

Respectfully submitted,

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